

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

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DANIELLE JENNINGS,

Petitioner,

v.

SECRETARY OF HEALTH  
AND HUMAN SERVICES,

Respondent.

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\* No. 16-779V  
\* Special Master Christian J. Moran  
\*  
\* Filed: July 8, 2020  
\* Reissued: April 20, 2021  
\* entitlement; human papillomavirus  
\* (“HPV”) vaccine; asthma/breathing  
\* problems; chronic fatigue syndrome;  
\* gastrointestinal dysfunction  
\*

Scott W. Rooney, Nemes, Rooney P.C., Farmington Hills, MI, for petitioner;  
Darryl Wishard, U.S. Dep’t of Justice, Washington, DC, for respondent.

### **UNPUBLISHED DECISION DENYING COMPENSATION\***

Danielle Jennings filed a petition for compensation under the National Childhood Vaccine Injury Compensation Program (the “Vaccine Act” or “Program”), 42 U.S.C. § 300aa—10 to 34 (2012), alleging that a human papillomavirus (“HPV”) vaccine she received caused her to develop various conditions, including asthma/breathing problems. Pet., filed June 30, 2016. Because Ms. Jennings has not established that she suffered from many of the conditions for which she seeks compensation and that the record supports a finding that her asthma/breathing problems existed before the vaccination, she is not entitled to compensation.

### **Procedural History**

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\* The parties were informed that this decision would be made available to the public. Ms. Jennings sought redaction of this decision, but her motions were denied. Orders, issued Oct. 19, 2020 and Sep. 15, 2020. After Ms. Jennings requested that the Court of Federal Claims review the orders denying redaction, the Court denied the motion for review. Order, issued Feb. 8, 2021. Accordingly, this decision is being posted as originally submitted, except for modification to this footnote.

Ms. Jennings began this case by filing a petition on June 30, 2016.<sup>1</sup> She filed a collection of medical records. The petitioner filed the first of six affidavits from Denise Jennings as exhibit 7 on October 3, 2016. In this October 3, 2016 affidavit, Ms. Jennings set forth a series of allegations about her daughter's health and school attendance. Exhibit 7. Some of the affidavit reproduces a chronology that appears in a medical record from January 2014. Exhibit 14 at 23-27. While the author of the chronology is not identified, the context suggests that Denise Jennings prepared this chronology.

Petitioner periodically filed medical records and other documents over the next six months. As discussed in the summary of events, the collection of medical records was not ideal as petitioner did not produce records from every office of every doctor who treated her. On April 5, 2017, petitioner represented that she was waiting for only one more set of medical records. Otherwise, the record was essentially completed. Pet'r's Status Rep., filed Apr. 5, 2017.

This status report allowed the Secretary to review the submitted material. The Secretary summarized the medical records. Resp't's Rep., filed May 1, 2017, at 2-8. After reviewing the standards for entitlement, the Secretary argued that petitioner had not established that Ms. Jennings was entitled to compensation. The Secretary "disputes that petitioner has demonstrated that vaccine-related injury." Id. at 9. The Secretary indicated that neither a treating doctor nor a retained expert offered any theory to explain how a vaccine caused Ms. Jennings's injury. Id. The Secretary also disputed the temporality in that some symptoms occurred before the vaccination and some diagnoses occurred months after the vaccination. Id. at 11.

After the Secretary recommended against compensation, to facilitate the drafting of reports from experts, the undersigned proposed a set of instructions for the expert. Order, issued May 23, 2017. The draft instructions later became final. Order, issued Aug. 2, 2017.

In a June 12, 2017 status conference, petitioner disputed the accuracy of some of the medical records, which the Secretary had summarized. Thus, Ms.

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<sup>1</sup> Initially, Denise Jennings, the mother of Danielle Jennings, acted as petitioner because Danielle had not reached the age of majority. However, Danielle eventually became the petitioner. Order, issued Aug. 23, 2018. Whether Denise Jennings or Danielle Jennings was the petitioner does not affect the outcome.

Jennings was given an opportunity to file an affidavit. She also requested an opportunity to file an amended petition. Order, issued June 14, 2017.

Petitioner first filed her amended petition. The amended petition alleges that Danielle Jennings “continues to suffer from a toxic reaction to the vaccinations as identified above.” Am. Pet., filed June 21, 2017, ¶ 11. The amended petition does not specify a particular disease or condition that the vaccinations allegedly caused. However, the amended petition does assert that after the vaccinations, Ms. Jennings experienced “hand numbness, headaches, handwriting difficulties, visual comprehension difficulties” as well as “memory impairments and neurologic impairments.” Id. ¶¶ 9-10.

Petitioner submitted affidavits from Denise Jennings on July 14, 2017 (exhibit 19) and September 1, 2017 (exhibit 20). The former discussed potential sources of information about Danielle’s health in the relevant time. The latter contested some of the material found in the medical records from Dr. Baptist. Petitioner also filed more medical records and school records.

Petitioner announced an intention to retain an expert. Pet’r’s Status Rep., filed Oct. 12, 2017. After multiple enlargements of time, petitioner filed the first report from Dr. Santoro on May 29, 2018. Exhibit 26. This report did not comply with the August 2, 2017 Expert Instructions. For example, Dr. Santoro did not define the condition that was affecting Danielle. Consequently, petitioner was ordered to obtain a supplemental report. Order, issued June 25, 2018.

This supplemental report from Dr. Santoro was filed on August 23, 2018. Exhibit 27. Dr. Santoro, again, did not reach a conclusion about Danielle’s diagnosis. Order, issued Sept. 17, 2018. The Secretary intended to file an expert report in response.

After similarly receiving multiple enlargements of time, the Secretary filed a report from Dr. MacGinnitie on February 14, 2019. Exhibit A. Dr. MacGinnitie challenged many aspects of Dr. Santoro’s opinion, including the lack of diagnosis. Id. at 4-5, 9.

Petitioner’s response to Dr. MacGinnitie’s report took place in two forms. Denise Jennings challenged some of Dr. MacGinnitie’s factual assertions in an affidavit. Exhibit 39. Dr. Santoro disputed some of Dr. MacGinnitie’s medical opinions in two more reports. Exhibits 40-41.

The Secretary filed another report from Dr. MacGinnitie on September 10, 2019. Exhibit P.<sup>2</sup> In the ensuing status conference, the parties stated that the stage for developing expert reports was finished. Accordingly, the parties were directed to file briefs regarding entitlement. Order, issued Sept. 25, 2019. This order allowed the parties to file a limited amount of additional information, including updated medical records for Danielle.

The parties complied. Petitioner filed her brief with additional evidence on March 4, 2020. Exhibits 42-53. The Secretary filed his brief on March 27, 2020. The Secretary, too, filed additional evidence. Exhibits U-Z. Although permitted additional time, petitioner did not file a reply. The case is ready for adjudication.

### **Standards for Finding Facts**

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa–11(c)(2). Medical records that are created contemporaneously with the events they describe are presumed to be accurate. Cucuras v. Sec’y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Not only are medical records presumed to be accurate, they are also presumed to be complete, in the sense that the medical records present all the patient’s medical issues. Completeness is presumed due to a series of propositions. First, when people are ill, they see a medical professional. Second, when ill people see a doctor, they report all their problems to the doctor. Third, having heard about the symptoms, the doctor records what he or she was told.

Appellate authorities have accepted the reasoning supporting a presumption that medical records created contemporaneously with the events being described

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<sup>2</sup> The Secretary also designated another document as exhibit P, a disciplinary action against Dr. Neuenschwander, that was filed on July 15, 2019.

are accurate and complete. A notable example is Cucuras in which petitioners asserted that their daughter, Nicole, began having seizures within one day of receiving a vaccination, although medical records created around that time suggested that the seizures began at least one week after the vaccination. Cucuras, 993 F.3d at 1527. A judge reviewing the special master's decision stated that "[i]n light of [the parents'] concern for Nicole's treatment . . . it strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred." Cucuras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993).

Judges of the Court of Federal Claims have followed Cucuras in affirming findings by special masters that the lack of contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. See, e.g., Doe/70 v. Sec'y of Health & Human Servs., 95 Fed. Cl. 598, 608 (Fed. Cl. 2010) (stating "[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), aff'd sub nom. Rickett v. Sec'y of Health & Human Servs., 468 Fed. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion); Doe/17 v. Sec'y of Health & Human Servs., 84 Fed. Cl. 691, 711 (2008); Ryman v. Sec'y of Health & Human Servs., 65 Fed. Cl. 35, 41-42 (2005); Snyder v. Sec'y of Health & Human Servs., 36 Fed. Cl. 461, 465 (1996) (stating "The special master apparently reasoned that, if Frank suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents' mention of it, would have been noted by at least one of the medical record professionals who evaluated Frank during his life to date. Finding Frank's medical history silent on his loss of developmental milestones, the special master questioned petitioner's memory of the events, not her sincerity."), aff'd, 117 F.3d 545, 547-48 (Fed. Cir. 1997).

The presumption that contemporaneously created medical records are accurate and complete is rebuttable, however. For cases alleging a condition found in the Vaccine Injury Table, special masters may find when a first symptom appeared, despite the lack of a notation in a contemporaneous medical record. 42 U.S.C. § 300aa-13(b)(2). By extension, special masters may engage in similar fact-finding for cases alleging an off-Table injury. In such cases, special masters are expected to consider whether medical records are accurate and complete. To overcome the presumption that written records are accurate, testimony is required

to be “consistent, clear, cogent, and compelling.” Blutstein v. Sec’y of Health & Human Servs., No. 90-2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998).

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims has identified four such explanations for explaining inconsistencies: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. La Londe v. Sec’y Health & Human Servs., 110 Fed. Cl. 184, 203 (2013), aff’d, 746 F.3d 1334 (Fed. Cir. 2014).

When weighing divergent pieces of evidence, special masters usually find contemporaneously written medical records to be more significant than oral testimony. Cucuras, 993 F.2d at 1528. Testimony offered after the events in question is less reliable than contemporaneous reports when the motivation for accurate explication of symptoms is more immediate. Reusser v. Sec’y of Health & Human Servs., 28 Fed. Cl. 516, 523 (1993). However, compelling oral testimony may be more persuasive than written records. Campbell, 69 Fed. Cl. at 779 (“[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking.”); Camery v. Sec’y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998) (this rule “should not be applied inflexibly, because medical records may be incomplete or inaccurate”); Murphy v. Sec’y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991) (“[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.”) (citation omitted), aff’d, 968 F.2d 1226 (Fed. Cir. 1992).

### **Finding of Facts**

Ms. Jennings was born in 2000 at 32 weeks gestation. Her early birth may have contributed to some respiratory issues. See exhibit 8 at 10, exhibit 25 at 48-49, 63. Otherwise, events in her first 12 years seem not to affect the outcome of this case. For example, her pediatrician, Marcia Newcombe, assessed her as a well

child in an August 20, 2011 examination. Exhibit 25 at 6.<sup>3</sup> Ms. Jennings's general good health had allowed her to play soccer since kindergarten. Id. at 29.

On March 9, 2013, the family brought home a golden Labrador Retriever. Exhibit 14 at 24 (chronology Denise Jennings apparently created in conjunction with an appointment on January 30, 2014).<sup>4</sup> As discussed briefly below, the Secretary's expert suggested that an allergy to this dog could have been responsible for Ms. Jennings's breathing problems. Exhibit A at 5-6.

Following the August 20, 2011 well-child appointment, Ms. Jennings's next appointment with her pediatrician was on March 23, 2013. The chief complaint was "pain in abdomen / chest / back after running for a few minutes x 1 month." Dr. Newcombe assessed her as having "exercise induced asthma" with "no vocal cord paralysis." Dr. Newcombe demonstrated how to use an inhaler and stated that if Ms. Jennings were not better with an inhaler, then she should seek testing with a pulmonologist. Exhibit 25 at 5. Dr. Newcombe recommended the first dose of the HPV vaccine. Id.; see also exhibit 1. Ms. Jennings asserts she had a mild reaction to the first dose of the HPV vaccine, given on March 23, 2013. However, she does not claim compensation for any injury related to the first dose. See Pet'r's Br. at 23, 38.<sup>5</sup>

In later medical records, doctors recorded histories from Ms. Jennings and her mother that Ms. Jennings developed asthma and/or breathing difficulties *after* the HPV vaccination. E.g., exhibit 6 at 10-13, 29-33. These histories are not correct. The March 23, 2013 record establishes that Ms. Jennings came to Dr. Newcombe because she was having breathing problems when she ran, resulting in

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<sup>3</sup> In June 2013, Ms. Jennings and her mother told a doctor that in January or February, Ms. Jennings was ill and tested for strep. She recovered from it completely. Exhibit 25 at 29. In August 2013, another doctor recorded a history that Ms. Jennings possibly had an influenza infection in January 2013. Exhibit 25 at 57. Similarly, in January 2014, two doctors were informed that in February 2013, Ms. Jennings experienced a febrile illness, either influenza or mononucleosis. Exhibit 6 at 42-44, exhibit 14 at 22-28. However, the set of records from the pediatrician contain no notes from January or February 2013, corroborating the accounts of illness.

<sup>4</sup> While much of the chronology is repeated in the initial affidavit of Denise Jennings (exhibit 7), the information about the family getting a new dog is not in the affidavit.

<sup>5</sup> The statute of limitations precludes compensation for an injury that developed shortly after the first HPV vaccination.

a diagnosis of “exercise induced asthma,” and a recommendation to consult a pulmonologist. Exhibit 25 at 5.

The pulmonologist whom Ms. Jennings saw was Martin Hurwitz from the West Bloomfield Asthma, Allergy, and Pediatric Pulmonology Center on May 14, 2013. Ms. Jennings and her mother told Dr. Hurwitz that “Since the beginning of the indoor soccer season last fall [2012], Danielle has experienced pressure sensation on the chest and lightheadedness and almost near syncope after 10 minutes of hard running.” Exhibit 25 at 61.<sup>6</sup> While Ms. Jennings reported that her symptoms were better during the outdoor soccer season, a bronchodilator inhaler was not effective. Dr. Hurwitz recorded that Ms. Jennings “is not allergic to any foods or medications” and that the family has two pet dogs. *Id.* at 62. Dr. Hurwitz tested Ms. Jennings’s pulmonary function with a spirometry. The results were below predicted rates. Dr. Hurwitz wanted an echocardiogram to see if Ms. Jennings might have any structural abnormalities.

To obtain the echocardiogram, Ms. Jennings saw a pediatric cardiologist, Elliott Weinhouse, on May 17, 2013. Dr. Weinhouse recounts that Ms. Jennings was a “very precious, 12-year-old young lady,” who has a “recent onset of chest pain with sports.” Exhibit 2 at 2; exhibit 25 at 34 (duplicate). Dr. Weinhouse administered an echocardiogram, which detected a small antero-inferior pericardial effusion. A “pericardial effusion” is the “accumulation of more than 50 mL of pericardial fluid in the pericardium.” Dorland’s Illustrated Medical Dictionary 589 (32nd ed. 2012). After a follow-up examination a few days later, Dr. Weinhouse opined that the pericardial infusion was a residual from a previous viral-like illness. Exhibit 2 at 4. He recommended no vigorous sports or gym class until Ms. Jennings was re-examined in a month.

Less than a month later, the family sought a second opinion regarding the pericardial effusion with a different pediatric cardiologist, Daniel R. Turner. Exhibit 3 at pdf 3-7. Dr. Turner’s report provides information about her cardiopulmonary function as well as information directly relevant to Ms. Jennings’s claim that the vaccination harmed her by causing her to develop headaches. Ms. Jennings wanted a second opinion because she had upcoming

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<sup>6</sup> Dr. Hurwitz’s record is an example of the disorganization of medical records. His May 14, 2013 report appears in the set of records of Dr. Newcombe. However, the report of the spirometry, a test to measure breathing, that Dr. Hurwitz administered is found in the high school records. Exhibit 12 at 12. It appears that petitioner did not produce a set of records directly from the West Bloomfield Asthma, Allergy, and Pediatric Pulmonology Center.



tryouts for a travel-league soccer team and wanted to know if exercise restrictions were necessary. Id. at pdf 4.

With respect to Ms. Jennings's breathing, Dr. Turner wrote that "Recently, Danielle started a new indoor soccer league and both Danielle and her mother noticed a marked difference in her exercise tolerance. . . . She sought medical attention for this and was recommended an albuterol inhaler, but according to Danielle it was tried and did not help." Exhibit 3 at pdf 3-4. Dr. Turner administered an electrocardiogram, echocardiogram, and exercise stress test. Id. at pdf 5-6. Based upon these studies, Dr. Turner reached an impression that Ms. Jennings had "Exercise-induced chest pain, noncardiac in nature, and likely related to asthma with response to albuterol." Id. at pdf 6. Dr. Turner referred Ms. Jennings back to her pediatrician for management of her asthma.

In addition to this detailed assessment of Ms. Jennings's cardiopulmonary function, Dr. Turner conducted a review of systems. In this context, Dr. Turner stated that Ms. Jennings "complains of headaches that occur every other day. They occur in the frontal areas and occasionally will spread back to the parietal and occipital areas in a band-like arrangement. . . . [S]he takes aspirin to treat the problem." Exhibit 3 at pdf 5. Dr. Turner's report appears to be the first time a doctor noted that Ms. Jennings was suffering headaches after the vaccination. Dr. Turner did not record how long Ms. Jennings was having headaches.

Ms. Denise Jennings averred that her daughter collapsed during a soccer game on or about June 8, 2013. Exhibit 7 at 1 (affidavit, sworn Oct. 3, 2016). However, medical records do not corroborate this account. On October 29, 2013, a pediatric neurologist, Iqbal Allarakhia, recorded a history that "About a year ago, while playing soccer, [Ms. Jennings] collapsed on the field although she did not lose responsiveness or awareness. She did not feel lightheaded or dizzy." Exhibit 22 at 36. Dr. Allarakhia's history is slightly supported by Dr. Turner's June 5, 2013 report before the alleged collapse in which Dr. Turner stated "There was one episode of near syncope when she [was] playing where she felt very dizzy. On that day, she was not sure if she had hydrated appropriately." Exhibit 3 at pdf 4. The context of Dr. Turner's report places this incident before 2013, possibly meaning the fall 2012. Ms. Jennings's expert, Dr. Santoro, does not cite this alleged collapse in his medical history nor does he assert syncope as one of the symptoms or injuries that Ms. Jennings suffered. Consequently, although Ms. Jennings may have collapsed sometime during 2012, the assertion about collapsing during a soccer game on or about June 8, 2013 is not credited.

Another reason for not accepting the assertion about a collapse on June 8, 2013, is that this incident is not memorialized in the well-child visit with Dr. Newcombe on July 5, 2013, approximately one month later. See exhibit 25 at 4. While the handwriting makes this report difficult to read, the doctor assessed Ms. Jennings as a “well teen.” She also has “exercise induced asthma.” Id. Dr. Newcombe recommended another dose of varicella and HPV. Id.; see also exhibit 1. This second dose, given on July 5, 2013, allegedly caused Ms. Jennings’s health problems. See Pet’r’s Br. at 1, 38; footnote 5, above.

Once more, there are allegations that Ms. Jennings’s health declined after the July 5, 2013 vaccination. E.g., exhibit 7 (Denise Jennings’s first affidavit) at 2; exhibit 39 (Denise Jennings’s sixth affidavit). Some medical records provide this history. Of this group, the earliest medical record was created by a holistic practitioner on January 30, 2014. Exhibit 14 at 21. However, Ms. Jennings has not submitted any medical records from later July or early August 2013, describing any health problems.

Instead, the next medical record after the July 5, 2013 well-child visit is an appointment with a pediatric pulmonologist, Lokesh Guglani, on August 27, 2013. Exhibit 25 at 56. Dr. Guglani states that he is seeing Ms. Jennings and her older sister, who provided a letter from their mother with a history, upon referral from Dr. Turner, the cardiologist. Ms. Jennings reported having breathing difficulty after 5-10 minutes of running during soccer games and requiring frequent substitutions when she had been playing recently. After obtaining a history, which is more-or-less consistent with the chronology above, and performing various tests, Dr. Guglani opined that Ms. Jennings might be suffering from vocal cord dysfunction, rather than exercise induced asthma. Id. at 59. He, accordingly, recommended breathing exercises and a possible referral to a speech therapist. Id.

It appears that in January 2014, Denise Jennings created a chronology stating that in early September 2013, her daughter’s “right hand was weak and she had difficulty writing or grabbing anything with power.” Exhibit 14 at 26; accord exhibit 7 (affidavit) at 4. However, in an October 29, 2013 medical record, a doctor stated, “This patient and her mother have not noticed [a] change in handwriting or clumsiness or any kind of subtle disequilibrium.” Exhibit 25 at 26. The October 29, 2013 record is more reliable because it was created closer in time.

Ms. Jennings returned to her pediatrician on September 23, 2013. The chief complaint was “chest pain x 1 night, pounding feeling, worse when walking, headaches.” Additional details are provided in different handwriting: “HA [headaches] 2-3x occurs while resting after CP [presumably chest pain] . . .

[positive] dizzy w/ HA, [no] abd. pain, pounding band-like HA; . . . ill 7 months ago when CP began; . . . HA starts in occipital region.” Exhibit 25 at 3. Due to the illegible handwriting, how Dr. Newcombe responded to the report of headaches is not entirely clear.<sup>7</sup> She seems to have described Ms. Jennings as a “well looking child.” Id.

An episode of chest pain while playing soccer prompted Ms. Jennings and her family to seek treatment at the emergency department of the Detroit Medical Center for the Children’s Hospital of Michigan on October 16, 2013. Exhibit 15 at 19-34. In one history, Ms. Jennings reported “‘shaking’ and ‘numbness’ of her hands occasionally, when she has episodes of chest pain.” Id. at 27. None of the reports from this emergency room visit suggest Ms. Jennings was having headaches. Ms. Denise Jennings reported that her daughter had a URI in January 2013, and after which developed chest pain and difficulty breathing with exercise. Id. One consulting physician—who might be a pulmonologist—stated, “I do think some of her symptoms are related to vocal cord dysfunction and I encouraged her to continue the relaxation exercises that were reviewed by Dr. Guglani and the speech therapists.” Id. at 31. Tests, such as chest X-rays, electrocardiogram, and pulmonology tests, were negative. See exhibit 14 at 26; exhibit 25 at 24.

After the visit to Children’s Hospital of Michigan, Ms. Jennings returned to see Dr. Hurwitz, the pediatric pulmonologist. Ms. Jennings and her mother informed Dr. Hurwitz that a doctor at the Children’s Hospital of Michigan suggested that she might have vocal cord dysfunction. Thus, Dr. Hurwitz requested records from the hospital so that he could evaluate the basis for that suggestion. Dr. Hurwitz recorded that Ms. Jennings’s chief complaint was chest pain with shortness of breath. Ms. Jennings also complained of “arm numbness and [having] trouble opening jars with her right hand. This began several weeks ago.” Exhibit 25 at 26. In addition to obtaining a release to acquire the records from the hospital, Dr. Hurwitz prescribed a medication and anticipated seeing Ms. Jennings about in one month.

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<sup>7</sup> Ms. Jennings’s retained expert, Dr. Santoro, stated that “The first manifestation of the headaches post-vaccination was the report of September [2013]. Exhibit 25, p. 3.” Exhibit 27 at 4. However, Dr. Santoro appears to overlook Dr. Turner’s June 5, 2013 report that Ms. Jennings was having headaches every other day. Exhibit 3 at pdf 5. Similarly, in an affidavit, Denise Jennings averred that her daughter “began complaining of headaches within the first two weeks after the vaccinations in July 2013.” Exhibit 39 ¶ 10. Ms. Jennings, too, seems to have missed the report of headaches to Dr. Turner in June 2013.

Ms. Jennings went to her pediatrician on October 25, 2013. The chief complaint was “R hand feels numb, headache.” Exhibit 25 at 2. Dr. Newcombe’s notes, which remain difficult to read, indicate that Ms. Jennings is “lt [light] sensitive” and has a “bad HA almost every day.” In reference to Ms. Jennings’s recent trip to the Children’s Hospital of Michigan, Dr. Newcombe recorded that a pulmonologist proposed vocal cord dysfunction, but the exercises were not helping. Ms. Jennings also recounted that her “R hand feels numb from HA” and she “can’t read handwriting.” It appears that Ms. Jennings was referred to a neurologist and ordered an MRI. See exhibit 22 at 22 (results of MRI).

Before the appointment with the neurologist, Ms. Jennings saw a specialist in allergies and immunology, Harvey Leo, on October 28, 2013. Exhibit 25 at 50.<sup>8</sup> Dr. Leo’s report begins with a statement that Ms. Jennings “has had a fairly complex past medical history.” Exhibit 25 at 48. His report elaborates on this topic in two respects. Dr. Leo recounts that Ms. Jennings “has been seen on several occasions because of recurrent shortness of breath issues with exercise. She has had a full cardiac workup and pulmonary workup by our pulmonology and cardiology colleagues.” Id. Dr. Leo stated that “They [apparently Ms. Jennings and her parents] also feel that symptoms worsened when the new dog . . . was brought into the home in the past year.” Id.<sup>9</sup> In addition, Dr. Leo noted that Ms. Jennings “has currently been evaluated for migraine headaches” and that she plays competitive soccer. Id.

Dr. Leo administered a skin prick test. The results showed “positive reactivity to grasses predominantly.” Exhibit 25 at 49. Dr. Leo concluded that Ms. Jennings “has evidence of allergic rhinitis, which is probably playing an overall role in the possibility of asthma-like issues. We suspect she does have some true asthma given her early birth history . . . . However, this may be confused with both vocal cord dysfunction.” Id. Dr. Leo recommended different medications to help when she had breathing difficulties.

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<sup>8</sup> Information about the date of this appointment is not consistent. While the last page states that Dr. Leo digitally signed his report on September 17, 2013, the appointment was on October 28, 2013. Exhibit 25 at 50; see also exhibit 14 at 26.

Like the records from Dr. Hurwitz, reports from Dr. Leo appear in only the records of Dr. Newcombe. It appears that petitioner did not file any records obtained directly from Dr. Leo’s practice, Allergy & Immunology Associates of Ann Arbor, P.C.

<sup>9</sup> While Dr. Leo’s report does not specify when the Jennings took in a new dog, Denise Jennings’s chronology states that this happened on March 9, 2013. Exhibit 14 at 24.

A pediatric neurologist, Iqbal Allarakhia, saw her on October 29, 2013. Dr. Allarakhia's record begins by stating that Ms. Jennings "two weeks ago had a severe headache during which she developed numbness of the right hand and also mild weakness of both hands, which lasted the whole day." Exhibit 22 at 36. Dr. Allarakhia provides details about Ms. Jennings's headaches. The frequency of severe headaches was "about once a month, usually in the morning." Id. "The headache starts in the occipital region, then develops like a band and involves the frontal region, squeezing in nature, not pulsatile without nausea, vomiting." Id. "The headache intensity averages at about 8/10." Id.

Dr. Allarakhia conducted an examination and reviewed the MRI, which Dr. Newcombe had ordered. He assessed her as having "Complicated migraine with numbness of the right hand." Id. at 37. He recommended that she avoid migraine triggers, such as insufficient fluid intake, skipping meals, stress, and insufficient sleep. Because her headaches were not very frequent, Dr. Allarakhia did not prescribe a prophylactic medication, but did prescribe Fioricet for when headaches started. Id.

When Ms. Jennings, with her mother and father, returned to Dr. Newcombe's pediatric group on November 16, 2013, they saw Dr. Ada Kendall. Exhibit 25 at 1.<sup>10</sup> Ms. Jennings or her parents were "very frustrated" by her lack of progress. Her headaches were worse and causing concentration problems at school.

Ms. Denise Jennings's chronology and affidavit mentions one doctor for which no records have been filed, Dr. Pittaway. Exhibit 14 at 26; exhibit 7 at 6. On November 19, 2013, Dr. Pittaway tested Ms. Jennings's digestive system and recommended various supplements, which Ms. Jennings had not started to take.<sup>11</sup>

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<sup>10</sup> While Dr. Kendall's full name does not appear in the medical records, Dr. Ada Kendall is listed as one of the pediatricians in the same medical group as Dr. Newcombe, Providence Park Pediatrics (<https://healthcare.ascension.org/Locations/Michigan/MIDET/Novi-Ascension-Medical-Group-Providence-Park-Pediatrics>). Dr. Kendall also appears to have signed the medical record for this visit. Exhibit 25 at 1.

<sup>11</sup> Ms. Jennings appears to be referencing Dr. Kenneth Pittaway of the Institute of Natural Health Sciences (<http://www.institutenhs.com/>). Dr. Pittaway is listed as having a N.D. (natural doctor) degree and a Ph.D. (specialty not identified) but does not appear to have a M.D. (medical doctor) degree. Ms. Jennings has not filed any records from the Institute of Natural Health Sciences.

According to Denise Jennings's chronology, Dr. Newcombe said "'her brain [was] misfiring and incorrectly signaling pain where none exists'" at a November 21, 2013 appointment. Exhibit 14 at 26.<sup>12</sup> Dr. Newcombe recommended seeing a psychologist for consultation and treatment.

Around November or December, Ms. Jennings had "daydreams, tune outs, and staring spells" that resolved by January 14, 2014. Exhibit 8 at 9. Around this time, according to Denise Jennings's chronology, her daughter's teachers and classmates noticed a change in her behavior and short-term memory loss. Exhibit 14 at 26. Ms. Denise Jennings wrote to her daughter's teachers on December 17, 2013, that Danielle was making slow progress. Exhibit 24 at 7.

Ms. Jennings started hyperbaric oxygen therapy on December 13, 2013. According to a patient information form, Ms. Denise Jennings learned about the Oxford Hyperbaric Therapy Center from a "friend/relative" and the reason for seeking treatment was "Gardasil Vaccination Poisoning." Exhibit 9 at 6. This notation appears to be the first instance Ms. Jennings, or a parent, linked Ms. Jennings's health problems with the vaccination. Ms. Jennings had 26 sessions of hyperbaric oxygen, lasting until January 20, 2014. Id. at 5.

The connection to the vaccination is also mentioned in the next report from the immunologist, Dr. Leo, on December 16, 2013. Ms. Jennings's family "has been very concerned about increasing episodes of memory loss, muscle weakness and chest pain. . . . These symptoms have escalated and they are now concerned about the amnesia and confusion as well as significant amount of sleep." Exhibit 25 at 43. "The family was concerned if the Gardasil was the triggering factor for these reactions. They would like to discuss the possibility of heavy metal testing and other testing components of the Gardasil. We informed the parents that there are no specific testing modalities at this time for the components of Gardasil aside from limited skin prick testing, which would not answer the particular issues they have." Id.

Dr. Leo appears to have taken these complaints, "particularly the memory loss issues and concerns about the vaccine" seriously. He suggested "several other explanations that should be pursued first before we identify the vaccine as a major cause." One possibility was autoimmune disease and vasculitis. Therefore, Dr. Leo ordered ANA profiles. Second, Dr. Leo wanted a sleep study to see whether sleep issues could be contributing to fatigue and memory loss. Third, Dr. Leo

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<sup>12</sup> The medical records for Dr. Newcombe's medical group (exhibit 25) do not contain a corresponding record for this appointment.

noted hypothyroidism was possible, although he doubted that problem because Ms. Jennings's weight had not changed. Fourth, Dr. Leo ordered tests to rule out mononucleosis. Finally, Dr. Leo recommended formal neuropsychological testing to document objectively any amnesia or memory loss. Exhibit 25 at 44.

A set of laboratory results from a blood draw on December 19, 2013, appear as exhibit 6, pages 20-24. The ordering doctor was Cheryl A. Johnstone of the Medical Clinic of Northville. In this context, there is no discussion of the significance of any results.

The first appointment for Ms. Jennings in 2014 was at the Michigan Institute for Neurological Disorders, where she saw John Manica, on January 14, 2014. Dr. Manica addressed his letter to Dr. Johnstone.<sup>13</sup> Dr. Manica obtained a history that is generally consistent with the history recounted above. Ms. Jennings was experiencing headaches daily that lasted all day.<sup>14</sup> Ms. Jennings further described her headaches as "pressure-like" and sufficiently painful to "bring tears" and to miss school one or two times per week.<sup>15</sup> Dr. Manica assessed her as "experiencing adolescent migraine headaches. . . . Her neurological examination is normal." Exhibit 8 at 10. Dr. Manica instructed Ms. Jennings to keep a headache journal and prescribed medication. He anticipated seeing Ms. Jennings again in about one month.

Dr. Manica also ordered an MRI of Ms. Jennings's brain and a routine awake EEG with hyperventilation and photic stimulation. Both these tests were normal. Exhibit 8 at 8, 13.

Ms. Jennings saw James Neuenschwander from the Bio Energy Medical Center on January 30, 2014. Denise Jennings explained that they saw Dr.

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<sup>13</sup> Petitioner has not filed any records obtained directly from Dr. Johnstone's office.

<sup>14</sup> Although Dr. Manica's history states Ms. Jennings developed headaches since March 2013, the first report of headaches was Dr. Turner's June 5, 2013 report.

<sup>15</sup> The middle-school records for the 2013-2014 academic year show that Ms. Jennings was absent from classes between 27 and 43 times per class. Denise Jennings's affidavit provides additional details about school absences. Exhibit 7 at 7-8. Nonetheless, all her grades were either A's or A minuses. Exhibit 24 at 3.

Neuenschwander because the family was having “difficulty getting a clear diagnosis from providers.” Exhibit 39 ¶ 15.<sup>16</sup>

It appears that in advance of this appointment Ms. Jennings prepared a detailed chronology to which this decision has cited. See exhibit 14 at 24-27. Based upon this history and information communicated orally, Dr. Neuenschwander assessed Ms. Jennings as suffering from reactive airway disease, toxic encephalitis, allergies, and fatigue syndrome. Id. at 22. He recommended various supplements. Id. at 23.

Following the January 30, 2014 appointment with Dr. Neuenschwander, it appears that Ms. Jennings saw doctors much less frequently. For example, it appears that Ms. Jennings did not have any appointments with her pediatrician, Dr. Newcombe, after November 21, 2013. See exhibit 14 at 26.<sup>17</sup> Similarly, Ms. Jennings did not file any records showing treatment in 2014 with the immunologist (Dr. Leo) or the pediatric pulmonologist (Dr. Hurwitz). A pediatric neurologist was expecting to see Ms. Jennings, but was, on February 18, 2014, waiting for Ms. Jennings to submit a headache questionnaire before scheduling an appointment. Exhibit 6 at 18. Whether Ms. Jennings did not see doctors, or she did not file records from doctors, such as Dr. Johnstone, whom she did see in this time, is difficult to determine. In any event, the record shows that Ms. Jennings saw Dr. Neuenschwander on March 31, 2014, and May 21, 2014. Exhibit 14 at 15, 18.

Around this time, Ms. Jennings also consulted with Mark Flannery, who is a chiropractor in California. Dr. Flannery describes himself as having experience in nutrition. On April 3, 2014, and May 8, 2013, Dr. Flannery ordered blood tests. See exhibit 11 at 5-15. While Ms. Jennings filed these test results as part of Dr. Flannery’s records, this exhibit contains no reports of office visits or evaluations. However, on October 27, 2014, Dr. Flannery wrote a two-paragraph letter “To Whom it May Concern,” which appears in Ms. Jennings’s high school records. Dr.

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<sup>16</sup> The Secretary filed a disciplinary complaint from the Michigan Department of Licensing and Regulatory Affairs, Board of Medicine, alleging that Dr. Neuenschwander improperly advised a patient regarding medical treatment. CM/ECF No. 133, attachment #1. Dr. Neuenschwander later entered into a consent order admitting to one count of negligence or failure to exercise due care and paid a punitive fine on May 20, 2015. (<https://aca3.accela.com/MILARA/GeneralProperty/LicenseeDetail.aspx?LicenseeNumber=4301050438&LicenseeType=Medical%20Doctor>).

<sup>17</sup> As noted above, the medical records for Dr. Newcombe’s pediatric group (exhibit 25) do not contain a corresponding record for this appointment.



Flannery stated that Ms. Jennings “has been diagnosed with a reaction to the Gardasil vaccine.” Exhibit 12 at 15.

Ms. Jennings saw a neurologist, Gireesh Velugubanti, on July 14, 2014. Exhibit 6 at 28.<sup>18</sup> Dr. Velugubanti note begins that Ms. Jennings was well until the first Gardasil vaccination on March 23, 2013 “when she developed difficulty in breathing that again began shortly after the vaccination.” Exhibit 6 at 28.<sup>19</sup> Dr. Velugubanti conducted a neurologic examination. His assessment included four parts. First, to rule out a partial seizure disorder, he ordered long-term video monitoring. Second, with respect to episodic memory loss, Dr. Velugubanti did not detect any memory impairments in the working or declarative domain of testing. Third, for headaches, Dr. Velugubanti recommended physical therapy. Fourth, he wanted to rule out conversion disorder. He stated: “I have reviewed side effects of Gardasil and did not identify any associations in the side effect profile. Vaccine associated damage is being worked up through Bioenergy Dr. Wine.” Id. at 32.<sup>20</sup>

Ms. Jennings underwent a three-day EEG, beginning on August 1, 2014. Dr. Velugubanti interpreted the EEG as “abnormal.” While the background was normal, there were “occasional interictal diffuse spike and polyspike and wave discharges throughout the recording.” Dr. Velugubanti suggested that Ms. Jennings might suffer from “juvenile myoclonic epilepsy / primary generalized primary epilepsy.” Exhibit 4 at 2. The next document from Dr. Velugubanti is a “To Whom it May Concern” letter, dated January 28, 2015, which is nearly six months later. While he states Ms. Jennings “has also been seen for multiple medical appointments” regarding headaches and migraines, there are no reports from any other appointment.

The neuropsychological evaluation recommended by Dr. Velugubanti was performed on August 27, 2014, by Allison Myers, a psychologist, and Annette Richard, an intern. Ms. Myers determined that Ms. Jennings’s performance on memory was “variable and suspected to be impacted by suboptimal

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<sup>18</sup> Exhibit 6 is the set of records from the University of Michigan Health System. Dr. Velugubanti’s July 14, 2014 report is a scanned or faxed copy. Records from the office of Dr. Velugubanti, Michigan Neurology Associates PC, do not contain the July 14, 2014 report. See exhibit 4.

<sup>19</sup> This report is not accurate. Dr. Newcombe recorded breathing problems on the day of vaccination. Exhibit 25 at 5.

<sup>20</sup> Dr. Neuenschwander’s organization is known as “Bio Energy.”

effort/disengagement.” Exhibit 5 at 5. Ms. Myers tied this performance to “a discrepancy between self-reported symptoms and known patterns of brain function as the patient reported frequent amnesia for recent events and sudden inability to read, cognitive symptoms which are not consistent with epilepsy or other neurological disorders.” Id. at 6. The diagnostic impressions were “unspecified neurocognitive disorder” and “[rule out] conversion disorder.” Id. at 11.

Before Ms. Jennings had the neuropsychological evaluation, Ms. Jennings saw another pediatric pulmonologist, Wan Chong Tsai, upon referral from Dr. Newcombe. Exhibit 22 at 4-10.<sup>21</sup> Dr. Tsai’s impressions included asthma, vocal cord dysfunction, allergic rhinitis, and “possible Gardasil vaccine-related neurologic adverse effect with report of new seizure onset under active evaluation currently.” Id. at 9.

On two days in December 2014, Ms. Jennings underwent a second neuropsychological evaluation at Dr. Velugubanti’s referral. Exhibit 12 at 16-25. The evaluator was Angela K. DeBastos, a pediatric neuropsychologist. Id. at 25.<sup>22</sup> Ms. DeBastos did not comment on Ms. Jennings’s effort or consistency of responses. Ms. DeBastos found that the results of her testing are “consistent with a cognitive disorder secondary to a history of non-convulsive seizure activity, chronic headaches and fatigue, and possible mild traumatic brain injury.” Id. at 20.

At the end of 2014, Ms. Jennings was involved in a car accident, but this accident does not affect her claim that a vaccine injured her. In 2015, Ms. Jennings periodically saw Dr. Neuenschwander, but these appointments also are not relevant. She may have seen Dr. Johnstone (see exhibit 6 at 48), but she did not file any records from Dr. Johnstone.

In 2016, Ms. Jennings saw two doctors, whose reports have some relevance to her claim. On April 29, 2016, she saw a doctor with a specialty in allergy and immunology at the University of Michigan Health System, Alan P. Baptist. The reason for the visit was “adverse reaction to HPV vaccine 3 years ago, this caused immunology and allergy issues. She has seen many other doctor[s], allergists, and

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<sup>21</sup> The filed records from Dr. Newcombe do not contain any reports from visits shortly before Ms. Jennings saw the pediatric pulmonologist.

<sup>22</sup> Ms. DeBastos’s report is found in the school records and was a basis for aspects of the section 504 plan. The school records do not contain the earlier neuropsychologic report from Ms. Myers. Likewise, Ms. DeBastos does not mention the previous report from Ms. Myers.

Mom would like to try to find out how to fix the issues this has caused.” Exhibit 6 at 9.

Dr. Baptist’s history begins inaccurately. His report states: “Mother states [Ms. Jennings] was doing well until the age of about 13. States that had no asthma, and got HPV vaccine in 2013. Notes that in soccer about 2 months later was having some breathing difficulties and was diagnosed w/ asthma. Also seemed to develop headaches.” Id. at 10. This sequence of events is wrong because Dr. Newcombe reported breathing problems on the day of the vaccination. See exhibit 25 at 6. Dr. Baptist also recounted that tests for allergies on multiple foods came back positive. Exhibit 6 at 10.<sup>23</sup>

Dr. Baptist’s history also states that Ms. Jennings “[h]as been diagnosed w/ chronic fatigue syndrome.” Id. at 10. This piece of information also appears mistaken as the doctor who diagnosed Ms. Jennings with chronic fatigue syndrome is not readily apparent. At best, Dr. Neuenschwander included a diagnostic code for “other fatigue.” Exhibit 14 at 14.

For current problems, Dr. Baptist recorded that “all foods give problems – fatigue, headache, abdominal pain.” Id. Ms. Jennings also has difficulty with breathing, including shortness of breath. For the food allergies, Dr. Baptist recommended a limited diet and then a food diary. Id. at 12. Dr. Baptist was concerned that Ms. Jennings might suffer from chronic fatigue syndrome and he recommended a pediatric rheumatologist.

For the family’s concern about the HPV vaccination, Dr. Baptist stated that “he spent considerable time . . . going over the literature regarding the HPV vaccine and autoimmune disease or neurologic disease. There are some studies that do not seem to support any increased incidence of autoimmune disease nor of neurologic disease after the vaccine.” Id.<sup>24</sup> “It is difficult for me to assess whether it truly was the vaccination or a coincidence that the symptoms occurred. There unfortunately is no clear way to determine this other than giving the vaccine [again] which of course the family is understandably reluctant to do.” Id. Dr. Baptist concluded his letter to Dr. Johnstone by saying that he would see Ms.

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<sup>23</sup> Dr. Neuenschwander ran a comprehensive food panel on January 5, 2016. Exhibit 14 at 2.

<sup>24</sup> Denise Jennings has challenged the accuracy of Dr. Baptist’s assertion that he reviewed literature about adverse effects of the HPV vaccine. Exhibit 20.

Jennings again on as-needed basis. Dr. Baptist also referred Ms. Jennings to a pediatric rheumatologist for treatment of possible chronic fatigue syndrome.

The second relevant record from 2016 was the record from a pediatric rheumatologist, Mark Hoeltzel. Dr. Hoeltzel came to the impression that Ms. Jennings suffers “numerous symptomatic complaints that do not fit well into a recognized pattern of rheumatologic disease. However, given the fact that no alternate etiology has been discovered, I think it is reasonable to perform [a] preliminary screen for underlying autoimmune disease.” Exhibit 18 at 10. Although Dr. Hoeltzel ordered laboratory testing, he planned not to see Ms. Jennings again because she did not have an underlying autoimmune disease.

The foregoing records were available to the doctors the parties retained, Drs. Santoro and MacGinnitie, when they wrote their reports. When the parties were instructed to file briefs regarding entitlement, Ms. Jennings was also ordered to file updated medical records. Order, issued Nov. 12, 2019.

In response, Ms. Jennings filed a single set of medical records, which were from Edward Conley of the Fatigue and Fibromyalgia Clinic. The records contain results of blood tests and Dr. Conley’s report of a visit on August 29, 2019. Exhibit 53.<sup>25</sup> Dr. Conley’s assessment was: “Chronic Fatigue [rule out] CFIDS. History of positive CMV? HHV6? Migraines. Asthma under treatment. Cognitive dysfunction. History of Seizures. Multiple other diagnoses.” *Id.* at 9. In Dr. Conley’s view, Ms. Jennings “had a neurological reaction to the Gardasil vaccine causing weakness/seizures.” Dr. Conley recommended a series of supplements. He also noted that Ms. Jennings was leaving for an unspecified college in New York in 48 hours. *Id.*

### **Standards for Finding Entitlement**

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

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<sup>25</sup> Ms. Jennings did not file any records for 2017 or 2018.

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

An element of a petitioner's case is to establish that the vaccinee suffered “at least one defined and recognized injury” and “not merely a symptom of manifestation of an unknown injury.” Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011). An allegation that the vaccinee had “dysethesia” or an “idiosyncratic severe reaction” does not satisfy this requirement. Lasnetski v. Sec'y of Health & Human Servs., 128 Fed. Cl. 242, 263 (2016) (denying motion for review), aff'd, 696 F. App'x 497 (Fed. Cir. 2017).

### Analysis

Here, Ms. Jennings has put forward multiple problems that the HPV vaccine allegedly caused. These problems can be grouped into two categories. For most conditions, Ms. Jennings has not satisfied the requirement to demonstrate that she suffers from a defined injury as explained in section A below. Thus, she cannot receive compensation for any of them. The remaining category consists of the one condition, breathing trouble, that she did suffer. While sufficient evidence establishes she suffered from some respiratory ailment, her breathing problems existed before the vaccination. See section B below. Finally, section C explains why a ruling on the papers is appropriate and a hearing is not necessary.

#### *A. Conditions Not Established*

The issue of diagnosis has run throughout this case. The Instructions to Experts particularly directed any expert to discuss the appropriate diagnosis by including, among other points, the diagnostic criteria for any disease that the expert proposes. Order, issued Aug. 2, 2017, ¶ 4. Dr. Santoro was required to prepare a supplemental report because his first report did not present a diagnosis. Order, issued June 25, 2018; see also exhibit 26 (Dr. Santoro's first report). Once the experts presented their opinions, the order for briefs in advance of adjudication again raised this issue. Order, issued Nov. 12, 2019, at 5. Ms. Jennings's brief did not address the topic of diagnosis in a separate section of her brief, making

identification of the injury that she alleges a vaccination caused more difficult. See Vaccine Rule 8(f) (waiver of arguments not specifically raised)

In one respect, the simplest point came from Dr. Santoro. He stated Ms. Jennings's "constellation of symptoms cannot be given a definitive disease diagnosis." Exhibit 41 at 1. This statement reflects the struggles of Ms. Jennings's treating doctors to identify the problem or problem from which she suffers. Ms. Jennings alleged numerous symptoms in the amended petition: exercise intolerance, asthma, hand numbness, headaches, handwriting difficulties, visual comprehension difficulties, reading difficulties, memory impairments, neurological impairments. Of those conditions, Dr. Santoro found support for headaches, reactive airway disease, fatigue/chronic fatigue syndrome, non-convulsive epilepsy, digestive disease, and cognitive/memory issues. Exhibit 27 at 2-8. On the other hand, Dr. Santoro took no position on toxic encephalitis and did not posit that petitioner suffered systemic inflammatory response syndrome. Id. at 5. Ms. Jennings brief seemingly narrows the list of relevant diseases to (1) asthma / allergic reaction, (2) chronic fatigue syndrome, and (3) gastrointestinal disease. Pet'r's Br. at 25-37 (discussing these conditions in the context of prong 2 of Althen). These conditions are considered in turn.

Asthma/allergic reaction. Ms. Jennings suffered problems with breathing.<sup>26</sup> Thus, resolution of this condition is deferred to section B below.

While Ms. Jennings links asthma to an allergic reaction, the claim that she suffered an allergic reaction stands on much shakier ground. She argues that she is allergic to a yeast component in the HPV vaccine and developed food allergies, particularly to gluten. Pet'r's Br. at 23-24. The brief cites no medical records to support these arguments. Dr. Santoro's August 21, 2018 report does not mention "yeast," and bases an opinion about food allergies on the affidavit from Denise Jennings. See exhibit 27 at 6. Dr. Santoro's June 4, 2019 report asserts that Ms. Jennings "developed an adverse reaction to yeast proteins after the July 2013 vaccination," exhibit 40 at 3, but provides no citation for this assertion. This report

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<sup>26</sup> Even for her breathing problems, the treating doctors appear not to have settled on a specific diagnosis for Ms. Jennings. Her pediatrician, Dr. Newcombe, diagnosed her as having "exercise induced asthma" on March 23, 2013. Exhibit 25 at 5. But after some attempts to treat asthma did not succeed, a pediatric pulmonologist, Dr. Guglani, suggested that Ms. Jennings might suffer from vocal cord dysfunction. Id. at 59. Dr. Leo noted that these conditions are often confused. Id. at 49. Dr. Neuenschwander assessed Ms. Jennings as suffering from reactive airway disease. Exhibit 14 at 22.

does not mention allergies. Finally, Dr. Santoro's August 3, 2019 report discusses neither yeast nor allergies. See exhibit 41.

In contrast, Dr. MacGinnitie has opined that Ms. Jennings has not demonstrated that she suffered from food allergies. Exhibit A at 9. Dr. MacGinnitie, who has specific expertise in allergy (see, exhibit B (curriculum vitae)), discounted any findings made by Dr. Neuenschwander. Although the testing from Dr. Neuenschwander could offer some superficial support that Ms. Jennings is allergic to certain foods, any such minimal support is so tenuous that neither Dr. Santoro nor Ms. Jennings has relied upon it.

Consequently, Ms. Jennings has not established, by preponderant evidence, that she suffers from food allergies.

Chronic fatigue syndrome. In her brief, Ms. Jennings maintains that she was diagnosed with chronic fatigue syndrome. However, these arguments are erroneous.

Ms. Jennings presents arguments about chronic fatigue syndrome in two places. First, she asserts she "has been diagnosed with Chronic Fatigue Syndrome after the 2013 vaccination. Exh. 22, p. 5. The onset was shortly after the second dosage." Pet'r's Br. at 24. This record does not support the proposition for which it is cited.

Page 5 of exhibit 22 is part of a seven-page report from Wan Chong Tsai, a pediatric pulmonologist, written on August 14, 2014. Page 5 contains no discussion of fatigue. However, on page 6, Dr. Tsai recounts that Ms. Jennings "denies any cough, wheezing, fatigue..." Exhibit 22 at 6. Consistent with Ms. Jennings's denial of fatigue, Dr. Tsai did not list chronic fatigue or anything like chronic fatigue among his impressions. See id. at 9. Thus, the first basis for the diagnosis of chronic fatigue syndrome does not sustain the argument.

Second, Ms. Jennings states she "did receive a diagnosis of chronic fatigue syndrome at the University of Michigan." Pet'r's Br. at 30, citing exhibit 6 at 11; accord exhibit 40 (Dr. Santoro's report) at 3; Pet'r's Br. at 9. This citation has some basis as Dr. Baptist was informed in 2016 as part of Ms. Jennings's history that Ms. Jennings "[h]as been diagnosed w/ chronic fatigue syndrome" and concluded that her "symptoms seem most consistent with chronic fatigue syndrome." Exhibit 6 at 10, 12.

However, crediting Dr. Baptist's conclusion is not possible. Preliminarily, the doctor who originally diagnosed Ms. Jennings as suffering from chronic fatigue

syndrome is not clear from Dr. Baptist's record or Ms. Jennings's brief. It seems that Dr. Baptist may have carried forward a diagnosis without much analysis. More significantly, Ms. Jennings did not complain about fatigue in many appointments after the vaccination. See exhibit 27 (Dr. Santoro's report) at 5 (describing instances in which Ms. Jennings did not complain of fatigue). Instead, she complained that her breathing problems were interfering with her attempts to compete in travel-level soccer. E.g., exhibit 25 at 61 (Dr. Hurwitz on May 14, 2013: Ms. Jennings "has experienced pressure sensation on the chest and lightheadedness and almost near syncope after 10 minutes of hard running"); exhibit 25 at 26 (reporting, at August 27, 2013 appointment, chest symptoms in soccer practices and games after running); exhibit 15 at 19-34 (emergency room visit on October 16, 2013 for collapsing while playing soccer); id. at 48 (Ms. Jennings reporting at October 28, 2013 appointment that she plays competitive soccer). Playing soccer is inconsistent with the fatigue associated with chronic fatigue syndrome. See McCabe v. Sec'y of Health & Human Servs., No. 13-570V, 2018 WL 3029175, at \*37-42 (Fed. Cl. Spec. Mstr. May 17, 2018) (discussing diagnostic criteria for chronic fatigue syndrome).

Accordingly, Ms. Jennings has not demonstrated, by a preponderance of evidence, that she suffers from chronic fatigue syndrome.

Gastrointestinal Disease. Compared with the allegations that Ms. Jennings suffered allergies or chronic fatigue syndrome, her claim that she suffered from gastrointestinal disease is even less developed. In the context of her Althen prong 1 argument concerning molecular mimicry, Ms. Jennings argues she "continues to suffer gastric problems that developed after the second dosage." Pet'r's Br. at 25. However, Ms. Jennings provided no citation to this assertion. Later, in the section on Althen prong 2, Ms. Jennings adds more argument about molecular mimicry. Id. at 33-37. Within this extended section, the only portion even loosely suggesting Ms. Jennings suffered from gastrointestinal problems is on page 35. There, Ms. Jennings asserts that she "also has developed gastrointestinal problems post-July 2013 vaccination. These problems first developed within four weeks after vaccination of July 2013." Again, the absence of any citation to a medical record is noticeable.

Dr. Santoro provides minimal support. In his August 21, 2018 report, Dr. Santoro states that Ms. Jennings has gastrointestinal problems based upon food allergies. Exhibit 27 at 6. The basis for this statement is Denise Jennings's affidavit, exhibit 7. Dr. Santoro's June 4, 2019 report asserts that Ms. Jennings "further developed gastrointestinal problems post-July 2013 vaccination. These problems first developed within four weeks after vaccination of July 2013," exhibit



40 at 3, but provides no citation for this assertion. Finally, Dr. Santoro's August 3, 2019 report provides no information that Ms. Jennings suffered from gastrointestinal problems. See exhibit 41.

Ms. Jennings has not identified any treating doctors who diagnosed her with any gastrointestinal disease. It appears that none of the doctors who treated Ms. Jennings referred her to a gastroenterologist and there are no records from a gastroenterologist who treated her. To the extent that Dr. Santoro has reached this diagnosis independently, Dr. Santoro seems to rely solely upon the affidavit of Denise Jennings, which is not a reliable basis for a diagnosis. Thus, Ms. Jennings has not established by preponderant evidence that she suffers from a gastrointestinal disease.

In sum, Ms. Jennings has not established that she suffered from allergies, chronic fatigue syndrome, or gastrointestinal disease. Absent this predicate, a full Althen analysis is not required. Hibbard v. Sec'y of Health and Human Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012).

### *B. Breathing Difficulties*

Ms. Jennings argues that she developed asthma and breathing problems after the first HPV vaccination in March 2013. She bases this argument upon her mother's affidavit, exhibit 7. Pet'r's Br. at 24, 26. As noted several times throughout the section summarizing Ms. Jennings's medical records, this chronology is not factually correct. Ms. Jennings had breathing problems when she came to Dr. Newcombe's office for the appointment in which she was given the first HPV vaccination. Exhibit 25 at 5. Thus, Ms. Jennings cannot prevail on a theory that the HPV vaccination caused her breathing difficulties. See Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380-81 (Fed. Cir. 2012).<sup>27</sup>

Ms. Jennings claim regarding breathing difficulties is being resolved based upon the pre-existing nature of those problems as Ms. Jennings has not claimed significant aggravation. In doing so, the undersigned is not determining how the evidence preponderates for other elements, including the role of any factors other

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<sup>27</sup> Conceivably, Ms. Jennings could have argued that the second HPV vaccination aggravated a pre-existing condition. However, although Denise Jennings states that her daughter's breathing problems were worse after the July 2013 HPV vaccination, Dr. Santoro has failed to present a minimally persuasive opinion regarding significant aggravation. See Wittner v. Sec'y of Health & Human Servs., 43 Fed. Cl. 199, 209 (1999) ("general statements that new symptoms appeared or became more severe 'following' each immunization are too vague to show on-Table onset or significant aggravation").

than a vaccine in causing her breathing difficulties. However, a preliminary view is that a factor other than a vaccine could explain Ms. Jennings's respiratory problems. Ms. Jennings first sought treatment for breathing problems from Dr. Newcombe approximately two weeks after the family brought a new dog into their home. See exhibit 25 at 48 (Dr. Leo's October 28, 2013 report). Dr. MacGinnitie suggested an allergy to dogs was a better explanation for Ms. Jennings's breathing problems. Exhibit A at 5-6. If this opinion were credited, then a factor unrelated to the vaccination would have caused her breathing problems.

*C. Resolution on the Papers is Appropriate*

The undersigned has reviewed the entire record.<sup>28</sup> Ms. Jennings retained Dr. Santoro, who presented opinions that Ms. Jennings suffered from various conditions for which there was little, if any, support in the contemporaneously created medical records. Instead, Dr. Santoro seems to have accepted the accuracy of an affidavit created years later. When there is a disparity between information in contemporaneously created medical records and affidavits, a special master is not required to hold a hearing to receive testimony from an expert. Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

**Conclusion**

Ms. Jennings has not established that she is entitled to compensation. The Clerk's Office is directed to enter judgment in accord with this decision unless a motion for review is filed.

**IT IS SO ORDERED.**

s/Christian J. Moran  
Christian J. Moran  
Special Master

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<sup>28</sup> While the collection of medical records appears to contain gaps in that Ms. Jennings seems to not have filed records from the offices of all doctors who treated her, such as Dr. Hurwitz, Dr. Leo, Dr. Pittaway, and Dr. Johnstone, the record is sufficient to evaluate her claim for compensation.